

446.006

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: :
JEAN LUC DUBOIS : Group: 1615
Serial No.: 09/202,217 :
Filed: December 9, 1998 :
For: NEW DEVICES...MEDICAMENTS :

475 Park Avenue South
New York, N.Y. 10016
April 13, 2005

RESPONSE

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

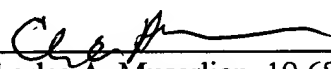
Responsive to the office action of December 16, 2004, Applicant requests reconsideration of the application in view of the remarks presented herein.

The Examiner has required a three way restriction requirement between claims 1 to 25 and 31 drawn to an adhesive matrix, claims 26 to 30 drawn to a method of manufacturing the device of group I and claim 32 drawn to esters of trimegestone. The Examiner deems that restriction is proper under PCT Rule 13.1 because they lack the same or corresponding special technical features since the matrix and the device of group I can be manufactured by hot melt extrusion and not by the method of group II and because group III is directed to a compound that is not required to be included in the transdermal matrix or device of group I.

Applicant respectfully traverses the restriction requirement since it is deemed that groups I and II should be examined in the same application under the Commissioner's order of February 28, 1996 relating to the treatment of product and process claims. It is deemed that the claims 26 to 30 which are drawn to the manufacture of the adhesive matrix of claims 25 to 31 should be properly joined together since they are of the same scope and if not examined together, they should be rejoined when the composition and product claims are deemed to be allowable since they are of the same scope. However, in order to be fully responsive to the office action, Applicant elects with traverse the claims of group I, namely, claims 1 to 25 and 31.

Since the first office action was merely a restriction requirement, a prompt examination on the merits is requested.

Respectfully submitted,
Muserlian, Lucas and Mercanti



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CAM:ds
Enclosures

OFFICIAL GAZETTE NOTICE

Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)

The purpose of this Notice is to provide guidance to Patent and Trademark Office personnel and to the public on the proper consideration of certain claims in light of In re Ochiai, **F.3d **, 37 USPQ2d 1127 (Fed. Cir. 1995) and In re Brouwer, **F.3d **, **USPQ2d **** (Fed. Cir. 1995) and the passage of 35 U.S.C. § 103(b), which became effective November 1, 1995. Ochiai, Brouwer and § 103(b) relate to how process claims directed to making or using nonobvious products are to be treated.

The Court in Ochiai and Brouwer addressed the issue of whether an otherwise conventional process could be patented if it were limited to making or using a nonobvious product. In both cases, the Federal Circuit held that the use of *per se* rules is improper in applying the test for obviousness under the 35 U.S.C. § 103. Rather, § 103 requires a highly fact-dependent analysis involving taking the claimed subject matter as a whole and comparing it to the prior art. To support a rejection under § 103, the collective teachings of the prior art must have suggested to one of ordinary skill in the art that, at the time the invention was made, applicant's claimed invention would have been obvious. In applying this test to the claims on appeal, the Court held that there simply was no suggestion or motivation in the prior art to make or use the nonobvious products to which the claims were limited and consequently overturned the rejections based upon § 103.

Interpreting a claimed invention as a whole requires consideration of all claim limitations. Thus, language in a process claim which recites making or using a nonobvious product must be treated as a material limitation, and a motivation to make or use the nonobvious product must be present in the prior art for a § 103 rejection to be sustained.

In light of Ochiai and Brouwer, Office personnel will consider all claim limitations when analyzing process claims which make or use nonobvious products under § 103. Office personnel will focus on treating claims as a whole and follow the analysis set forth in Graham v. John Deere, 383 U.S. 1, 148 USPQ 459 (1966).

Accordingly, to facilitate examination under § 103, where product and process claims are presented in the same application, applicant may be called upon under 35 U.S.C. § 121 to elect claims to either the product or process. The claims to the non-elected invention will be withdrawn from further consideration. However, in the case of an elected product claim, rejoinder will be permitted when a product claim is found allowable and the withdrawn process claim depends from or otherwise includes all the limitations of an allowed product claim. Withdrawn process claims not commensurate in scope with an allowed product claim will not be rejoined. In the event of rejoinder, the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104 - 1.106. If the application containing the rejoined claims is not in condition for allowance, the subsequent Office action may be made final, or, if the application was already under final rejection, the next Office action may be an advisory action.

35 U.S.C. § 103(b) is applicable to biotechnological processes only. Section 103(b) precludes a rejection of process claims which involve the use or making of certain nonobvious biotechnological compositions of matter under § 103(a). Section 103(b) requires that

1. the biotechnological process and composition of matter be contained in either the same application or in separate applications having the same effective filing date;
2. both the biotechnological process and composition of matter be owned or subject to an assignment to the same person at the time the process was invented;
3. a patent issued on the process also contain the claims to the composition of matter used in or made by the process, or, if the process and composition of matter are in different patents, the patents expire on the same date;
4. the biotechnological process falls within the definition set forth in § 103(b); and
5. a timely election be made to proceed under the provisions of § 103(b).

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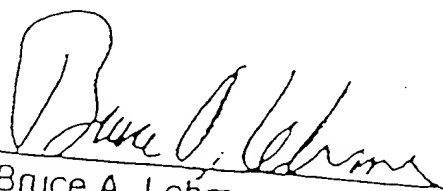
In view of the Federal Circuit's decisions in Ochiai and Brouwer, an applicant's need to rely upon § 103(b) should be rare. Consequently, the Patent and Trademark Office will treat § 103(b) elections on a case-by-case basis by way of petition under 37 CFR 1.182. That petition must establish that all the requirements set forth in § 103(b) have been satisfied. An election will normally be considered timely if it is made no later than the earlier of either (1) the payment of the issue fee, or (2) the filing of an appeal brief in an application which contains a composition of matter claim which has not been rejected under 35 U.S.C. §§ 102 or 103.

In an application where at least one composition of matter claim has not been rejected under 35 U.S.C. §§ 102 or 103, a § 103(b) election may be made by submitting the petition and an amendment requesting entry of process claims which correspond to the composition of matter claim.

For applications pending on or after November 1, 1995, in which the issue fee has been paid prior to the date of this Notice, the timeliness requirement for an election under § 103(b) will be considered satisfied if the conditions of 37 CFR 1.312(b) are met. However, if a patent is granted on an application entitled to the benefit of § 103(b) without an election having been made as a result of error without deceptive intent, patentees may file a reissue application to permit consideration of process claims which qualify for § 103(b) treatment.

Any questions, comments or suggestions regarding petitions under 37 CFR 1.182 filed pursuant to this Notice should be directed to the Special Program Law Office, attention: Hiram Bernstein, Senior Legal Advisor. All other questions, comments or suggestions regarding this Notice should be directed to the Solicitor's Office, attention: Craig Kaufman, Associate Solicitor.

Date: FEB 28 1996


Bruce A. Lehman
Assistant Secretary of Commerce and
Commissioner of Patents and Trademarks